THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 61

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL D. BARBERE

Appeal No. 97-0684
Application 08/171,343[1]

HEARD: October 14, 1997

Before ABRAMS, STAAB and McQUADE, *Administrative Patent Judges*.

STAAB, *Administrative Patent Judge*.

DECISION ON APPEAL

Michael D. Barbere (appellant) appeals from the final rejection of claims 1, 4-9, 13 and 14, which constituted all the claims remaining in the application at the time of final rejection. Subsequent to the final rejection an amendment canceling claims 8 and 9 was entered. Thus, only the final

[1] Application for patent filed December 22, 1993.

rejection of claims 1, 4-7, 13 and 14 remain before us for review. We *reverse.*

Appellant's invention pertains to a two tube, two lumen coaxial balloon dilation catheter for use in percutaneous transluminal coronary angioplasty. According to appellant, with some prior art catheter constructions,

> [t]he tortuous configuration of the arteries may present difficulties to the physician in properly placing the guidewire and then advancing the catheter over the guidewire. . . . For example, . . . there may be a tendency for the tubes to telescope when presented to an increased resistance. The telescoping of the tubes will tend to draw the ends of the balloon together slightly but sufficiently to permit the balloon to become bunched up as it is forced through the stenosis. The bunching up of the balloon makes it more difficult for the balloon to cross the stenosis. [specification, pages 3-4].

Appellant endeavors to overcome this alleged deficiency in the prior art by anchoring the distal end of the outer tube to the inner tube at a location within the balloon to prevent telescoping of the outer tube over the inner tube at the location of the balloon. According to appellant, "[b]y preventing telescoping of the inner and outer tubes, the axial distance between the ends of the balloon does not contract and bunching of the balloon is avoided" (specification, pages 5-6).

Independent claim 1 is illustrative of the appealed subject matter, and reads as follows:

1. A two tube, two lumen coaxial balloon dilation catheter comprising:

an elongate, flexible catheter shaft having a proximal region, a proximal end and a distal end, wherein the shaft is formed from an inner tube defining a guidewire lumen therethrough, and a surrounding outer tube coaxial with the inner tube and defining an annular inflation lumen therebetween, the inner tube being of smaller diameter than the outer tube and having a distal end region extending distally of the distal end of the outer tube;

an inflatable dilation balloon having a proximal end and a distal end, the proximal end of the balloon being attached to the distal region of the outer tube, the distal end of the balloon being attached to the distal region of the inner tube at a distal connection;

the outer tube being attached to the inner tube at a location between the proximal region of the catheter shaft and said distal connection to resist axial telescoping of the inner tube with respect to the outer tube when the catheter is advanced against a resistance at the distal region of the catheter, the outer tube terminating proximally of said distal connection;

means for communicating the annular inflation lumen with the interior of the balloon to facilitate inflation and deflation of the balloon, the inflation lumen comprising the sole lumen in communication with the interior of the balloon; and

means at the proximal end of the catheter for accessing each of the guidewire and inflation lumens.

The references of record relied upon by the examiner as evidence of obviousness are:

Simpson et al. (Simpson)	4,323,071	Apr. 6, 1982
Sugiyama et al. (Sugiyama) (Japanese Patent)	88/04560	Jun. 30, 1988[2]

Claims 1, 4-7, 13 and 14 stand rejected under 35 U.S.C. § 103 as being unpatentable over Simpson in view of Sugiyama, "each in view of the other." The examiner's rationale in support of this rejection is as follows:

> Attaching the Simpson et al. inner and outer tubes together in order to provide a more sturdy connection between the tubes would have been obvious in view of the Sugiyama et al. teaching of securing the tubes together (with the spacer and opening 11 as shown by Sugiyama et al. fig. 6 for example) apparently in order to provide such a sturdy connection.
>
> Alternatively, using only two coaxial tubes in the Sugiyama et al. catheter in order to simplify it and reduce its cost would have been obvious in view of the Simpson et al. teaching of using only two tubes. In other words, replacing the vent path B of Sugiyama et al. with a removable vent tube as shown by Simpson et al. at 156 in order to reduce the profile of the catheter would have been obvious. [answer, page 3].

Simpson pertains to a two tube, two lumen coaxial balloon dilation catheter comprising an inner tube 37 defining a guidewire lumen therethrough, and a surrounding outer tube 38

[2]Translation attached.

coaxial with the inner tube and defining an annular lumen 44 therebetween. The outer tube includes an integrally formed, thinned-walled, distensible balloon-like portion 43 intermediate its ends. The distal end of the outer tube is heat shrunk onto the distal end of the inner tube to provide a fluid tight seal between the inner and outer tubes. In Figure 12, Simpson discloses a catheter embodiment that includes a flush tube in the form of a thin flexible tubular wire 156, the purpose of which is to facilitate rapid filling of the balloon portion with a radiographic liquid and ensure that all air within the balloon portion can escape and be vented prior to introduction of the catheter into the patient (column 12, lines 29-54). When all air has been flushed from the catheter, the flush wire is removed (column 12, lines 60-61). Simpson does not disclose an outer tube terminating proximally of the distal end of the catheter and being attached to an inner tube at a location between the proximal and distal ends of the catheter to resist axial telescoping of the inner tube with respect to the outer tube, as required by independent claim 1.

Sugiyama pertains to a three tube, three lumen coaxial balloon dilation catheter comprising an inner tube 1 defining a guidewire lumen A therethrough, a surrounding intermediate tube 2

coaxial with the inner tube and defining an annular lumen B therebetween, and a surrounding outer tube 3 coaxial with the intermediate tube and defining an annular lumen C therebetween. An expandable balloon 10 is provided at the distal end of the catheter and is connected at its proximal end to the outer tube and at its distal end to the distal end of the catheter. The annular lumens B and C are in fluid communication with the interior of the balloon such that when contrast medium is injected into one of the annular lumens to inflate the balloon, any air remaining in the balloon can be easily flushed out through the other annular lumen (translation, page 7). Sugiyama discloses several embodiments, including a Figure 2 embodiment wherein the outer tube extends past the proximal end of the balloon and is directly secured to the intermediate tube, a Figure 5 embodiment wherein the ends of the outer and intermediate tubes are not secured to their respective underlying tubes such that annular lumens B and C communicate with the interior of the balloon by way of annular openings at the ends of the outer and intermediate tubes, a Figure 6 embodiment wherein the outer tube extends past the proximal end of the balloon and is indirectly secured to the intermediate tube via a spacer (not numbered), and a Figure 7 embodiment wherein the intermediate and

outer tubes are secured to each other and to the inner tube at the distal end of the catheter and the annular lumen B communicates with the interior of the balloon via radially extending ports 12. Sugiyama does not disclose a catheter wherein the inflation lumen (i.e., annular lumen C) is the sole lumen in communication with the interior of the balloon, as required for independent claim 1.

Considering first the examiner's position that it would have been obvious to one of ordinary skill in the art to attach the inner and outer tubes of Simpson together in view of Sugiyama's teaching of securing tubes together (with, for example, a spacer and opening 11 as shown by Sugiyama in Figure 6), the difficulty we have with this rationale is that we fail to see any teaching in the references themselves of an incentive for the proposed modification. Nothing in Simpson indicates that the construction illustrated, for example, in Figure 6, is for the purpose of providing a more robust connection between the outer and intermediate tubes, notwithstanding the examiner's unsupported statement that this construction is "apparently in order to provide such a sturdy connection" (answer, page 3). Moreover, providing such a construction in Simpson would appear to run counter to one of Simpson's stated objective, namely, forming the

balloon as an integral part of the outer tube so that balloon portions can be readily and reliably formed (column 2, lines 12-20).

Of course, if Simpson and Sugiyama were combined in the manner proposed by the examiner, the resulting catheter may very well function to resist bunching up of the balloon as it is forced through stenosis, as taught by appellant. This fact, however, does not provide the proper motivation for combining the teachings of these references. It is the teachings of the prior art taken as a whole which must provide the motivation or suggestion to combine the references. *See Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988), *cert. denied* 488 U.S. 825 (1988); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985) and *In re Deminski*, 796 F.2d 436, 442-43, 230 USPQ 313, 315-16 (Fed. Cir. 1986). Here, only appellant has suggested a two tube, two lumen balloon catheter having the outer tube terminating proximally of the distal end of the catheter and being attached to the inner tube to resist axial telescoping of the tubes with respect to each other when the catheter is advanced against a resistance at the distal region of the

catheter. As the court stated in *Uniroyal,* 837 F.2d at 1051, 5 USPQ at 1438, "it is impermissible to use the claims as a frame and the prior art references as a mosaic to piece together a facsimile of the claimed invention." This is precisely what the examiner has done here, in our view. It follows that we cannot support the examiner's first theory of obviousness.

We now take up for consideration the examiner's alternative position that it also would have been obvious to one of ordinary skill in the art to replace the vent path B of Sugiyama with a removable vent tube as taught by Simpson at element 156 in order to simplify the catheter, reduce its profile, and reduce its cost. The difficulty we have with this rationale is that it runs directly contrary to Sugiyama's expressly stated purpose of providing a triple-tube type catheter in order to *eliminate* the need for Simpson's removable vent tube and the alleged problems caused thereby. In this regard, we note the following passage from pages 4-5 of the Sugiyama translation:

> In Simpson-Robert type systems, due to the presence of the metal pipe for air bubble removal, the flexibility of the catheter is impaired, and, as with the Gruntzig type, there is the danger of injury to the blood vessel walls in blood vessels which are highly curved. In addition, there is also the possibility of the metal pipe breaking through the catheter.

> . . . The present invention . . . has the purpose of offering a vessel-expanding catheter which is able to eliminate residual air bubbles in the expanding member easily . . . [and] has the further purpose of offering a vessel-expanding catheter which prevents injury to the interior wall of blood vessels, thus reducing complications such as abrasion of the blood vessel interior walls . . .
>
> The aforesaid purposes are achieved by means of a vessel-expanding catheter characterized as being provided with a triple-tube type catheter tube composed of an inner tube that forms a No. 1 flowpath open at one end, a center tube that encloses said inner tube and forms a No. 2 flowpath with said inner tube, and an outer tube that encloses said inner tube and forms a No. 3 flowpath with said inner tube . . .

Thus, Sugiyama clearly teaches away from the modification thereof proposed by the examiner in his alternative theory of obviousness.

The decision of the examiner is reversed.

REVERSED

NEAL E. ABRAMS Administrative Patent Judge	)	
LAWRENCE J. STAAB Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
JOHN P. McQUADE Administrative Patent Judge	)	

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